

## **REMARKS**

The Office Action dated November 17, 2003 has been carefully considered. Claims 1-4, 11 and 12 are pending in the present application. Claims 1-3 have been amended. Claims 5-10 and 13-44 are withdrawn.

Applicant thanks the Examiner for the interview granted to applicant's representative, Linda B. Azrin, Reg. No. 44,516, on January 28, 2004. The remarks herein are consistent with those made during the interview. As proposed during the interview, independent claim 1 has been amended to incorporate the language "and projecting from," originally found in dependent claim 2. The language "projecting from the struts and" has been deleted from dependent claim 2.

Moreover, the recitation in claim 3 that the non-structural elements "are located along the stents" has been deleted since this term is believed to be redundant of the term "projecting from the stents" which has now been incorporated into claim 1, upon which claim 3 depends.

The amendments to claims 1-3 are fully supported by the specification as originally filed and, thus, no new matter has been introduced. Reconsideration of the present application in view of the following remarks is respectfully requested.

### **I. CLAIM REJECTIONS UNDER 35 U.S.C. § 102(e)**

Claims 1 and 12 have been rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,562,065 to Shanley ("Shanley"). This rejection is respectfully traversed.

Independent claim 1, as amended, recites a "medical device for delivering a biologically active material to a body tissue of a patient in need of treatment, wherein the medical device comprises a plurality of struts and a plurality of non-structural elements integral with and projecting from the struts, wherein the struts and the non-structural elements comprise the biologically active material." (Emphasis added). Claim 12 depends upon claim 1 and therefore includes all of the recitations of claim 1.

As discussed in the interview, Shanley does not disclose or suggest "non-structural elements integral with and projecting from the struts" as recited in the present claims. As stated in the specification, the non-structural elements have substantially no effect on the mechanical properties of the stent. Moreover, unlike the holes in Shanley, the non-structural elements of the present invention project from the strut. (*See, e.g.*, page 8, line 20 of the specification.) In addition, the non-structural elements can be used to increase the surface area of the stent, and thus vary the distribution of the biologically active material. (Page 15,

lines 1-6 of the specification). Moreover, the non-structural elements comprise the biologically active material. (Page 7, lines 30-31 of the specification). Also, the “non-structural elements are integral with the struts, namely, they are generally made from the same material as the struts and are formed as a continuous part of the struts.” (Page 8, lines 24-26 of the specification).

In contrast, Shanley teaches struts that have laser drilled holes therein for containing a beneficial agent. (Col. 14, lines 50-51). Figure 11 of Shanley shows a laser drilled hole 182 in the strut 88. As discussed in the interview, Shanley merely removes material from the strut and, thus, does not disclose or suggest the inclusion of non-structural elements integral with the struts as recited in the present claims. It is respectfully submitted that the “hole” disclosed in Shanley is not a non-structural element and therefore cannot be considered to be a non-structural element integral with a strut. By disclosing laser drilled holes in the struts to remove material from the struts, Shanley teaches away from the medical device of the present invention which includes, in addition to the struts, non-structural elements integral with the struts.

Even assuming for the sake of argument that the holes 182 are non-structural elements, which they are not, Shanley does not disclose or suggest that the struts and the non-structural elements comprise the biologically active material. Shanley discloses that the agents can be disposed “on the struts or within the struts.” (Col. 14, lines 45-48). However, Shanley does not disclose or suggest that both the struts themselves comprise an agent and that the holes also contain the agent. As stated above, Shanley does not even disclose or suggest, and, in fact, teaches away from the use of non-structural elements.

Thus, it is believed that claim 1 and the claims depending thereon are patentable over Shanley. Accordingly, withdrawal of this rejection and allowance of claims 1 and 12, are respectfully requested.

## **II. CLAIM REJECTIONS UNDER 35 U.S.C. § 103(a)**

### **A. Claims 3-4 Are Patentable Over Shanley**

Claims 3 and 4 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Shanley. This rejection is respectfully traversed.

For the reasons discussed above, it is believed that claim 1 and the claims depending thereon, which include claims 3 and 4, are patentable over Shanley. Thus, withdrawal of this rejection and allowance of claims 3 and 4 are respectfully requested.

**B. Claim 11 Is Patentable Over Shanley  
In View Of U.S. Patent No. 6,506,437 to Harish *et al.***

Claim 11 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Shanley in view of U.S. Patent No. 6,506,437 to Harish *et al.* (“Harish”). This rejection is respectfully traversed.

Claim 11 depends upon claim 1, which recites that “the medical device comprises a plurality of struts and a plurality of non-structural elements integral with the struts, wherein the struts and the non-structural elements comprise the biologically active material.” Claim 11 further recites that “the biologically active material is selected from the group consisting of paclitaxel, actinomycin, sirolimus, tacrolimus, everolimus, dexamethasone, halofuginone and hydrophobic nitric oxide adducts.” Since claim 1 was shown above to be patentable over Shanley, it is believed that claim 11, which depends upon claim 1, is also patentable over Shanley. As stated above, Shanley does not even disclose or suggest, and, in fact, teaches away from the use of non-structural elements.

Furthermore, Harish does not remedy the deficiencies of Shanley. Harish discloses a device that has depots formed in the outer surface thereof. (Col. 3, lines 32-33). Also, Harish discloses applying a composition including a therapeutic substance into the depots. (Col. 2, lines 19-20). However, the depots are not non-structural elements since they are formed from removal or absence of material in the outer surface. Thus, like Shanley, Harish does not disclose or suggest a non-structural element integral with and projecting from the struts and therefore does not disclose non-structural elements comprising a biologically active material.

Thus, Shanley and Harish, taken alone or in combination, do not disclose or suggest (1) non-structural elements that are integral with and project from the struts and (2) struts and non-structural elements that both comprise the biologically active material as required by the present claims.

Accordingly, it is believed that claim 11 is patentable over Shanley and Harish. Thus, withdrawal of this rejection and allowance of claim 11 is respectfully requested.

**III. ALLOWABLE SUBJECT MATTER**

The Examiner has objected to claim 2 as allegedly being dependent upon a rejected base claim, but stated that claim 2 would be allowable if rewritten in independent form to include all of the limitations of the base claims and any intervening claims. Although Applicant disagrees with this objection, claim 2 has been amended to delete the language

“projecting from the struts and,” which subject matter has been incorporated into claim 1 as “and projecting from.” For the reasons discussed above, it is believed that claim 2 is patentable over the cited references. Thus, withdrawal of this rejection and allowance of claim 2 are respectfully requested.

#### IV. CONCLUSION

Since all objections and rejections to the claims are believed to be overcome, all claims are believed to be in condition for allowance. An early notice to that effect would be appreciated. Should the Examiner not agree with Applicant's position, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the application.

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Respectfully submitted,

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